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EXAMINER	
MARSCHEL, A	
ART UNIT	PAPER NUMBER
1807	18

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FOLEY & LARDNER
ATTN: MR. STEPHEN BENT
1800 DIAGONAL RD.
P.O. BOX 299
ALEXANDRIA, VA 22313-0299

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run 5 mos ~~or continues to run~~ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 4/20/92 has been considered with the following effect, but it is not deemed to place the application in condition for allowance.

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☒ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☒ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☒ They raise the issue of new matter. (See Note).

   d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☒ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: the proposed claim 20 lacks the limitation to "human" receptor protein and therefore it raises the new issue of a broader scope than the originally filed application as well as being NEW MATTER embodied in said broader scope. Also see additional NOTES to Item #1 attached.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

   Claims allowed: none
   Claims objected to: none
   Claims rejected: 1-7 and 16-19

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The ~~affidavit, exhibit or request for reconsideration has~~ REMARKS have been considered but does not overcome the rejection because of reasons explained in the attachment section giving a further explanation to Item #4.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other It is noted that non-elected claims 8-15 are still pending.

Amelia B. Yarbrough
AMELIA BURGESS YARBROUGH
PRIMARY EXAMINER
ART UNIT ~~187~~ 1807

PTOL-303 (REV. 5-89)

Additional NOTES for Item # 1 of the attached Advisory Action:

The proposed claims 20 and 21 also raise the new issue of indefiniteness by citing a DNA "sequence" as the claimed composition. This citation is indefinite because a "sequence" is a property of a nucleic acid molecule and not a composition. In other words a "sequence" is a series of symbols for the bases present in said nucleic acid.

Proposed claims 20 and 21 also raise the new issue of indefiniteness as to the scope of practice that is meant for the word "hybridizes" cited in line 1 of both claims. It is well known in the art that a wide variety of hybridization conditions may be practiced. At very low stringency virtually any nucleic acids will hybridize to any other. At high stringency the sequence similarity between hybridizing nucleic acids must be correspondingly high. Since claims 20 and 21 do not cite a stringency limitation, they are indefinite as to what scope is meant. Therefore the set of nucleic acids that fall within the scope of these claims is indefinite.

Proposed claim 21 raises the new issue of a lack of enablement as to plasmid pHF1. It is noted that a deposit has been made at the ATCC under the Budapest Treaty including a statement of irrevocable public availability on the last page of the REMARKS filed 4/20/92. This is incomplete for enablement if there is insufficient written description in the specification to define the plasmid insert. Pages 10 and 20 are pointed to by applicants as containing support. The page 10 citation only

states that HF1 is a cDNA clone containing T11 sequences. This description clearly lacks any significant definition of recognizable HF1 characteristics especially since T11 has not been disclosed as having been sequenced and only sketchily restriction mapped as given in Figure 2. In Figure 2 there are only 3 restriction sites shown within HF1. On page 20 pHF1 is described as containing a 3.9 kbp insert but with other descriptive features that lack anything usable for clear identification purposes. For example, is there only one 6.4 kb RNA transcript is normal human fibroblasts? What hybridization conditions were used? Also virtually all human mRNAs contain a polyadenylation signal plus a poly(A) tail. It is not at all clear from Figure 2 that HF1 contains the coding sequence of T11 as stated on page 20, lines 18-19. What does the term "related to" mean as to the definition of the "170 nucleotides" segment? Due to these indefiniteness aspects, the only way of clearly identifying a nucleic acid as being HF1 or not is by obtaining the ATCC deposit for comparison which is deemed unreasonable for the determination of infringement, for example. This clearly supports the conclusion that the specification lacks enablement of pHF1 due to a lack of written description.

Further explanation from Item # 4 of the attached Advisory Action:

To reiterate, the REMARKS filed 4/20/92 are non-persuasive in overcoming the rejection based on 35 U.S.C. § 112, first paragraph, as summarized in the Final office action mailed

11/19/91. First, the non-entry of the amendment filed 4/20/92 causes claim 17 to remain pending. The T11 clone composition is not only essential material for claim 17 but it also is within the scope of the remaining claims 1-7, 16, 18, and 19. For example, claim 1 clearly includes a nucleic acid that encodes human type α PDGF receptor protein as T11 does. Claim 2 cites the word "according" to Figure 3. The word "according" does not limit the claimed composition to the Figure 3 segment because a reasonable interpretation of "according" is that the claimed composition contains the Figure 3 segment plus introns, for example. It is noted that applicants did not cite the phrase "consisting of" in claim 2. The inclusion of T11 practice in the remaining claims exists via a similar analysis. In summary, since T11 remains specifically claimed as well as included in the other claims and lacks enablement for reasons of record given in the office action mailed 11/19/91, the rejection under 35 U.S.C. § 112, first paragraph of claims 1-7 and 16-19 is maintained.

It is noted that an ATCC deposit number has been communicated along with a statement of public availability but that said ATCC number has not been amended into pending claim 17 to fill in the blank therein.

Applicants argue that the present specification teaches a repeatable method for obtaining the disclosed clones and probes. This assertion is non-persuasive due to a lack of factual evidence, especially in view of the confusion as to what the T11 clone actually consists of as previously discussed in the office

action mailed 11/19/91. The citation of clones pHF1 and pHB15 and related discussion in said argument lacks persuasive weight in view of the above discussed lack of written description for pHF1 which supports a conclusion of a lack of enablement for pHF1 as well as similarly applied for pHB15.

Applicants go on to argue that the confusion regarding T11 is mooted by the cancellation of claim 17. It is noted that claim 17 has not been cancelled due the non-entry of the amendment filed 4/20/92 as discussed above with regard to Item # 1 of the instant Advisory Action. Applicants further argue that "the T11 genomic clone is fully described and enabled in their specification as filed...". They argue that Figure 2 represents the T11 restriction map from which the nucleotide sequence of Figure 3 derives. This is non-persuasive since TR4 (supposedly the nucleic acid having the sequence of Figure 3) is shown in Figure 2 as containing two Kpn I restriction sites whereas there is only one such Kpn I site shown at the rightmost portion of exon b in the inset from T11. Where is the other one that is present in TR4? Also what happened to the Sac I site in exon b of T11? One direct interpretation is that only <u>one</u> restriction site, the Kpn I site of exon b, in T11 is reproduced in the TR4 composition sequenced and shown in Figure 3. How can applicants state the following as based on <u>one</u> restriction site: "Figure 2 represents the restriction map for the T11 genomic clone <u>from which</u> (emphasis added by Examiner) the nucleotide sequence of Figure 3 derives."? Applicants then argue that the Examiner

asserts that T11 contains only exons a, b, and c. Applicants apparently misinterpreted the statement by the Examiner that is given on page 3 of the office action mailed 11/19/91 with regard to a, b, and c. The Examiner pointed to the discussion of a, b, and c given in Figure 3, not Figure 2. This conflict originally was discussed in the first full paragraph of page 4 of the office action mailed 1/23/91. In Figure 3, there is an a, b, and c section depicted between nucleotides numbered 2641 and 3019. This clearly conflicts with what is depicted as exons a, b, and c shown in the inset portion of T11 of Figure 2. This conflict is the basis for the Examiner's comment on page 3 of the office action mailed 11/19/91. Applicant argue further that the fact the T11 terminates with EcoR I sites is irrelevant to Figure 3. The Examiner agrees with regard to Figure 3 but the content of T11 is what is being questioned and so the termini of T11 are highly relevant.

Applicants argue on page 5 of the REMARKS filed 4/20/92 that claim 20 does not recite clone T11 but rather a DNA that "...hybridizes with a specific deposited oligonucleotide probe.". The Examiner hereby points out that "specific hybridization" to a defined probe is quite different from generic "hybridization" to a "specific probe". The unclear scope of the claimed specificity of hybridization practice is discussed above with regard to various stringency conditions and makes said argument based on claim 20 (presently non-entered) additionally non-persuasive in overcoming the present rejection.

The Examiner wishes to point out that the amendment filed 4/20/92 has been denied entry as a whole to prevent confusion. Therefore neither the Abstract nor the specification has been amended via said 4/20/92 filed paper.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).
The CM1 Fax Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

AM

A. MARSCHEL:am

May 8, 1992